RVD2008-07

Re-evaluation Decision

Bentazon

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Overview

Re-evaluation Decision

After a re-evaluation of the herbicide bentazon, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing bentazon.

An evaluation of available scientific information found that products containing bentazon do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of bentazon uses, new risk-reduction measures must be included on the labels of products containing bentazon.

The regulatory approach for the re-evaluation of bentazon was first presented in Proposed Re-evaluation document PRVD2007-14, *Re-evaluation of Bentazon*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of bentazon as well as summarizes the Agency's decision and the reasons for it.

Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-14. To comply with this decision, registrants of products containing bentazon will be informed of the specific requirements affecting their product registrations and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Bentazon, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA is taking a regulatory decision and is requiring appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy (TSMP)).

The USEPA re-evaluated bentazon and published its conclusions in a 1994 RED as well as in the USEPA Federal Register document, *Bentazon: Pesticide Tolerance, 7 February 2002.*

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation section of the related Proposed Re-evaluation Decision, PRVD2007-14, *Re-evaluation of Bentazon.*

What Is Bentazon?

Bentazon is a herbicide used to control weeds in food/feed crops. Bentazon is also registered for weed control on turf (golf course, sod farm). Bentazon is applied using ground and aerial equipment by farm workers and professional applicators. Appendix II lists all products containing bentazon that are registered under the authority of the *Pest Control Products Act.*

Health Considerations

Can Approved Uses of Bentazon Affect Human Health?

Bentazon is unlikely to affect your health when used according to revised label directions.

People could be exposed to bentazon through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that bentazon was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Bentazon is currently registered in Canada for use on the following commodities:

- soybeans
- dry and snap common beans
- dry edible beans (in the Red River Valley of Manitoba only)
- peas
- lima beans
- fababeans
- corn (grain, silage, sweet and seed)
- flax (including low linolenic acid varieties)
- peanuts
- blueberries
- spring wheat (excluding durum)
- snow peas

As noted, bentazon may be used on other crops in other countries that are imported into Canada. MRLs for bentazon are established for the following commodities:

- peas at 3.0 ppm
- beans at 0.5 ppm
- barley, leeks, onions and wheat at 0.1 ppm
- blueberries, corn, flax, peanuts, rice and soybeans at 0.05 ppm

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Bentazon Is Introduced Into the Environment?

Bentazon is unlikely to affect non-target organisms when used according to revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to bentazon in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of bentazon was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the situation in Canada, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require terrestrial buffer zones for end-use products containing bentazon to protect terrestrial non-target plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of bentazon, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Limitation to two applications per year for turf
- Advisory label statement to reduce potential groundwater contamination
- Buffer zones to protect non-target sensitive terrestrial plants

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection[3] regarding this decision on bentazon within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

References[4]

List of Studies/Information Submitted by Registrant

PMRA 1319511	2004, Bentazone Manufactured by BASF AG Ludwigshafen Factory W 29 and analyzed by the Routine Quality Control Laboratory V5 of Agricultural Products Production Department BASF Aktiengesellschaft, Limburgerhof, Germany, DACO: 2.13.3
PMRA 1319514	2004, Spectra of Bentazone Reg.-No. 51929 (PAI), PCP03184, DACO: 2.14.13
PMRA 1319515	1988, Data Concerning the Physical and Chemical Characteristics of Basagran Manufacturers Concentrate - 600 g/L, DACO: 2.14.1, 2.14.10, 2.14.11,2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.16
PMRA 799710	1994, Bentazone TC: Description of the Manufacturing Process, N/S, MRID: N/S, DACO: 2.11.1
PMRA 799711	1993, Bentazon TGAI: Product Identity and Composition, Report No. 3912, MRID: N/S, DACO: 2.11.2,2.11.3,2.11.4

[4] These references are in relation to the chemistry section of PRVD2007-14. They are included in this document because the PMRA reference numbers were not yet available at the time of publication of PRVD2007-14.

Appendix I Comments and Responses

1.0 Comment on Chronic Risk to Birds

In Section 3.2.1 of PRVD2007-14, it is stated that there is "potential for chronic risk to birds" and a maximum of two applications per year on turf is therefore required. The registrant argues that this is not correct and should be revised based on additional avian studies. The additional avian studies were conducted by the registrant as recommended in the 1994 RED, to increase the certainty of chronic risk to birds, and were submitted to the PMRA with this comment.

Response

The statement in PRVD2007-14 on chronic risk to birds accurately summarizes the conclusion in the USEPA RED. The label restriction to a maximum of two applications per year on turf was based on a chronic risk to birds, as well as the risk to terrestrial plants. The additional studies submitted would not change the label restriction because there is still a need to protect non-target plants.

Although these additional studies were not reviewed at this time, they may be used to support future applications.

2.0 Comment on Incorrect Units for Seasonal Cumulative Rate

In Section 3.2.1 (Environmental Risk Assessment) of PRVD2007-14, the document states: "The maximum seasonal cumulative rate of bentazon was calculated as 3.6 kg ai/ha." This is not correct. The maximum seasonal cumulative rate of bentazon was calculated as 3.6 lbs a.i./acre.

Response

The PMRA agrees that the maximum seasonal cumulative rate of bentazon was calculated as 3.6 lbs a.i./acre in the USEPA RED, which corresponds to a maximum seasonal cumulative rate of bentazon of 4.0 kg a.i./ha. This does not affect the outcome of the re-evaluation decision.

3.0 Comment on Buffer Zone Table for Product with Reg. No. 12221

There appears to be an error in row 2 of the buffer zone table listed on page 22 in Appendix III of PRVD2007-14 for Reg. No. 12221. The crops alfalfa and seedling forage legumes/grass should be removed from row 2 as they are already captured in row 1.

Response

The PMRA agrees that this was an error. The corrected version of this label amendment can be found in Appendix III of this document.

Appendix II Current Canadian Registered Products Containing Bentazon as of 1 January 2008

Registrant	Registration Number	Guarantee	Product Name	Formulation Type	Class
BASF Canada Inc.	12221	480 g/L	Basagran Liquid Herbicide	Solution	Commercial
BASF Canada Inc.	16641	200 g/L bentazon 200 g/L atrazine	Laddok Herbicide	Suspension	Commercial
BASF Canada Inc.	20898	640 g/L	Technical Bentazon (Basagran)	Solution	Technical
BASF Canada Inc.	22006	480 g/L	Basagran Forte Liquid Herbicide	Solution	Commercial

Appendix III Label Amendments for Products Containing Bentazon

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) On the primary display panel of all end-use product labels, the following statement must be added:

POTENTIAL SKIN SENSITIZER.

II) The **DIRECTIONS FOR USE** section of end-use product labels must be amended to specify a maximum number of applications of two per year to turf.

III) The following statements must be included in the **PRECAUTIONS** section:

Potential skin sensitizer.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

DO NOT enter or allow worker entry into treated areas for 12 hours following application.

IV) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

The use of this chemical may result in contamination of groundwater, particularly in areas where soils are permeable (e.g. sandy soil) or the water table is shallow.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands), or to estuarine/marine habitats.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

V) For the product with Reg. No.12221, the following statements must be included in the **DIRECTIONS FOR USE** section:

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply when wind speed is greater than 8 km/h at flying height at the site of application. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length MUST NOT exceed 65% of the wing or rotorspan.

Buffer zones:
Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer, interrow hooded sprayer, spot treatment, soil drench and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:
			Terrestrial Habitat
Field sprayer*	Snow peas, peas (field and processing), seedling forage grasses/legumes and established forage legumes (for seed production)		1
	Turf, soybeans, corn, peanuts, beans (snap, lima, faba), dry beans, flax, newly planted fruit trees, blueberries, spring wheat		2
Aerial	Dry common beans	Fixed and rotary wing	20
	Soybeans, snap beans	Fixed wing	35
		Rotary wing	30

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VI) For the product with Reg. No.16641, the following statements must be included in the **DIRECTIONS FOR USE** section.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:
The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:
		Terrestrial Habitat
Field sprayer*	Corn (silage, grain, sweet, seed)	2

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

VII) For the product with Reg. No. 22006, the following statements must be included in the **DIRECTIONS FOR USE** section.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:
The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of: Terrestrial Habitat
Field sprayer*	Forage sorghum and forage millet	1
	Soybeans, corn, dry beans, fababeans, peas, flax	2

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

The label amendments presented above do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.